

Remarks

Claims 1, 2, 9-11 and 38-42 are pending in the subject application and currently before the Examiner. By way of this amendment, claims 1, 2, 9-11 and 38-42 have been canceled and claims 43-78 have been added. Support for the newly added claims can be found in the original and previously pending claims. Accordingly, favorable consideration of claims 43-78 is respectfully requested.

Applicants note that the Advisory Action issued on July 17, 2008 indicates that the last amendment filed in this matter (dated May 29, 2008) has not been entered in this matter. However, Applicants note that the terminal disclaimer and previously presented claim amendments were deemed to have resolved certain double patenting issues previously raised in this application. Accordingly, Applicants respectfully request entry of the previously filed after final amendments in this matter to resolve those double patenting issues and the subsequent entry of this amendment in response to the rejections of record.

Claims 1, 2, 9, 10 and 38-42 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action argues that Applicants have shown the formation of particular co-crystals, such as those recited within claim 11, but do not exemplify the formation of all co-crystals containing any solid API and any-co-crystal former that is liquid or solid and where the components are hydrogen bonded to one another or co-crystals with any of the numerous and diverse different co-crystal formers recited in claim 2 or the APIs recited within claim 6. The Office Action also indicates that the specification describes only the preparation of the particular co-crystals recited within claim 11 and does not describe the claimed invention in a manner sufficient to convey that the inventors were in possession of the entire claimed invention, including the formation of co-crystals containing any API and any co-crystal former that are hydrogen bonded.

Claims 1, 2, 9, 10 and 38-42 are also rejected under 35 U.S.C. §112, first paragraph, as nonenabled by the subject specification. The Office Action acknowledges that the specification is enabled for the preparation and use of the particular pharmaceutical co-crystals, but it is not enabled for the preparation of all co-crystals having any API that is solid, and any co-crystal former that is solid and liquid, where components are hydrogen bonded to one another, or all co-crystals having the

numerous and diverse APIs and co-crystal formers. Thus, the specification fails to provide sufficient support for the broad recitation of a co-crystal composition containing any solid API, in general, with any solid or liquid co-crystal-former, in general, in which the components are hydrogen bonded to each other.

Applicants respectfully maintain that the claimed invention complies with both the written description and enablement requirements of section 112; however, in order to advance prosecution in this matter the rejected claims have been canceled thereby rendering these issues moot. Accordingly, reconsideration and withdrawal of the rejections is respectfully requested.

Claims 1, 2, and 10 are provisionally rejected on the ground of nonstatutory “obviousness-type” double patenting over claims 86-93 of copending Application No. 10/546,963. Applicants, again, respectfully submit that a nonstatutory “obviousness-type” double patenting rejection for the instantly claimed invention should be withdrawn since it would not appear that the co-crystals recited in the currently pending claims would be obvious in view of the broader class of co-crystals claimed by specific functional groups in the ‘963 application; however, in the interest of expediting prosecution in this matter, a terminal disclaimer was filed in a previous response (dated May 29, 2008) and the entry of that paper and the terminal disclaimer is respectfully requested. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1, 2, 9-11, and 38-42 are provisionally rejected on the ground of nonstatutory “obviousness-type” double patenting over claims 1-49 and 72-87 of copending Application No. 10/570,405. With respect to this rejection, Applicants, again, respectfully submit that this nonstatutory “obviousness-type” double patenting rejection should be withdrawn as the scope of the currently pending claims does not include modafinil co-crystals. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1, 2, 9-11, and 38-42 are provisionally rejected on the ground of nonstatutory “obviousness-type” double patenting over claims 66-72 of copending Application No. 10/551,014 and over claims 2-7, 16, and 18 of copending Application No. 10/926,842. Applicants, again, respectfully submit that each of these rejections is inapplicable to the presently claimed invention as the scope of the claims no longer includes co-crystals of olanzapine or itraconazole. Accordingly, reconsideration and withdrawal of these rejections is respectfully requested.

Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

A handwritten signature in black ink, reading "Frank C. Eisenschenk", with a long horizontal flourish extending to the right.

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